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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,340	10/24/2000	Mary E. Brunkow	240083.501D4	3183

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/697,340	BRUNKOW ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-23,35 and 36* is/are pending in the application.

4a) Of the above claim(s) *35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 12/30/02 (Paper No. 14), is acknowledged.

Claims 20-23 and 35-36 are pending.

2. Newly submitted claim 35 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention of the elected group IV, claims 20-23, now claims 20-23 and 36 is related to a method of detecting the presence of mouse Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2 using antibody that specifically binds to Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2 . The invention of newly added claim 35 is related to a method of detecting the presence of human FKH^{sf} encoded by amino acid sequence of SEQ ID NO:4 using antibody that specifically binds to FKH^{sf} encoded by amino acid sequence of SEQ ID NO:4. The inventions of claims 20-23, 36 and claim 36 are different methods because they are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 35 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 20-23 and 36 are under consideration in the instant application.

In view of the amendment, filed 12/30/02 (Paper No. 14) the following rejections remain:

3. Claims 20-23 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2 using anti- Fkh^{sf} antibody or an antibody fragment that can bind to Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2 does not reasonably provide enablement for a method of detecting the presence of any Fkh^{sf} or any mutant form thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims essentially for the same reasons set forth in the previous Office Action, paper NO:13, mailed 09/30/02.

The claims as written encompass the genus of antibodies that can specifically bind polypeptides wherein such polypeptides have numerous differences in amino acid sequences at different position that were not disclosed (mutant form of Fkh^{sf})including numerous differences in linear and conformational epitopes.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing .

Applicant asserts that as disclosed in the specification and recited in the claims, the claimed invention was fully enabled because antibody that specifically bind to an Fkh^{sf} may be generated by a method disclosed in the specification and that using said antibodies a person skilled in the art may make and use the claimed method for detecting the presence of such polypeptides in a biological sample.

Contrary to Applicant assertions, as was stated in the previous Office Action, it is the examiner position that the specification disclosed only variant of Fkh^{sf} encoded by SEQ ID NO: 2. The common attributes of the Fkh^{sf} are not described. The specification does not provide sufficient guidance of any Fkh^{sf} polypeptide or any mutant form thereof . There is no description of mutation sites that exist in nature and there is no description of how the structure of mutant form relates to the structure and function of Fkh^{sf} encoded by SEQ ID NO: 2. The issue raised by the examiner was not if a person skill in the art can make and use antibody, but rather that only antibody that can specifically binds to Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2, but not to any Fkh^{sf} polypeptide or any mutant form thereof was enabled by the disclosure. Thus, only a method of detecting the presence of Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2 using anti- Fkh^{sf} antibody or an antibody fragment that can bind to Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2 was enabled.

4. Claims 20-23 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention essentially for the same reasons set forth in the previous Office Action, paper NO:13, mailed 09/30/02.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing .

Applicant asserts that the disclosure of the polynucleotide sequence (Seq ID NO 1) and the deduced amino acid sequence (SEQ ID NO:2) of the novel Fkh^{sf} polypeptide provides specific, detailed and complete chemical formulas, thus applicant is in possession of the claimed method of detecting the presence of an Fkh^{sf} .

Contrary to applicants assertion, as was stated in the previous Office Action, it is the examiner position that:

Applicant is in possession of a method of detecting the presence of Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2 using anti- Fkh^{sf} antibody or an antibody fragment that can bind to Fkh^{sf} encoded by amino acid sequence of SEQ ID NO:2.

Applicant is not in possession of a method of detecting the presence of any Fkh^{sf} or any mutant form thereof in a biological sample.

Applicant has disclosed a limited number of species. There is no description of mutation sites that exist in nature and there is no description of how the structure of mutant form relates to the structure and function of Fkh^{sf} encoded by SEQ ID NO: 2. Moreover, there is no description in the specification as filed for a method of detecting the presence of mutant Fkh^{sf} comprising a step of contacting the biological sample with antibody, or antibody fragment thereof, that specifically binds to a mutant Fkh^{sf} polypeptide encoded by a polynucleotide comprising (i) the sequence set forth in SEQ ID NO:1 and (ii) an insertion of the complement of a TT dinucleotide into a region of SEQ ID NO:1, said region comprising the complement of the sequence set forth in SEQ ID NO:12. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of a genus of polypeptide sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The following new ground of rejection is necessitated by the amendment filed 12/30/02 (Paper No. 14

5. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

A method of detecting the presence of mutant Fkh^{sf} comprising a step of contacting the biological sample with antibody, or antibody fragment thereof, that specifically binds to a mutant Fkh^{sf} polypeptide encoded by a polynucleotide comprising (i) the sequence set forth in SEQ ID NO:1 and (ii) an insertion of the complement of a TT dinucleotide into a region of SEQ ID NO:1, said region comprising the complement of the sequence set forth in SEQ ID NO:12 claimed in 36 represent a departure from the specification and the claims as originally filed. The specification and the claims as originally field only support a method of detecting the presence of mutant Fkh^{sf} polypeptide, comprising a step of contacting biological sample with anti- Fkh^{sf} antibody or an antibody fragment thereof.

Applicant's amendment, filed 12/30/02 (Paper No. 14) directs support to page 3, line 25-30; page 10, line 26 and page 35, lines 20-30 for the written description for the above-mentioned "A method of detecting the presence of mutant Fkh^{sf} comprising a step of contacting the biological sample with antibody, or antibody fragment thereof, that specifically binds to a mutant Fkh^{sf} polypeptide encoded by a polynucleotide comprising (i) the sequence set forth in SEQ ID NO:1 and (ii) an insertion of the complement of a TT dinucleotide into a region of SEQ ID NO:1, said region comprising the complement of the sequence set forth in SEQ ID NO:12 ". However, the passages pointed by the applicant do not provide a clear support for the now-claimed limitation of "A method of detecting the presence of mutant Fkh^{sf} comprising a step of contacting the biological sample with antibody, or antibody fragment thereof, that specifically binds to a mutant Fkh^{sf} polypeptide encoded by a polynucleotide comprising (i) the sequence set forth in SEQ ID NO:1 and (ii) an insertion of the complement of a TT dinucleotide into a region of SEQ ID NO:1, said region comprising the complement of the sequence set forth in SEQ ID NO:12 ".

6. No claim allowed

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
February 10, 2003

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